

FINAL REPORT OF AN AUDIT CARRIED OUT IN ITALY COVERING  
ITALY'S MEAT INSPECTION SYSTEM

APRIL 15, 2002 THROUGH MAY 16, 2002

Food Safety and Inspection Service  
United States Department of Agriculture

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Ministry of Health, Department General for Food, Nutrition and Public Veterinary Health)
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>

## 1. INTRODUCTION

The audit took place in Italy from April 15 to May 16, 2002. The audit team was comprised of one team leader and three auditors from the headquarters of FSIS located in Washington, DC, and three veterinary medical officer auditors from FSIS' Technical Service Center located in Omaha, Nebraska.

Audit team members were accompanied during the entire audit by representatives from the Central Competent Authority (CCA) and/or representatives from the regional and local inspection offices.

An opening meeting was held on April 15, 2002 in Rome with the CCA. At this meeting, the audit team leader confirmed the objectives and scope of the audit, the itineraries of the audit members, and requested additional information needed to complete the audit of Italy's meat inspection system.

## 2. OBJECTIVES OF THE AUDIT

The first objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States. The second objective of the audit was to determine if the CCA had taken the necessary corrective actions in response to previous audit findings. If so, Italy would be permitted to continue to ship product to the United States. If not, Italy would be suspended indefinitely from eligibility to ship product to the United States.

In pursuit of these objectives, the following sites were visited: the headquarters of the CCA, four regional inspection offices, one autonomous provincial office, six local health units, four laboratories performing analytical testing on United States-destined product, six swine slaughter establishments, and 35 meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	4	
	Autonomous Province	1	
	Local	6	Establishment level

### 3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to 41 establishments: six slaughter establishments and 35 processing establishments. The third part involved visits to four government laboratories, three of which were conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella*, and the fourth laboratory was planning to analyze such samples. The fourth part involved visits to four regional inspection offices, one autonomous provincial office, and six local inspection offices.

Program effectiveness determinations of Italy's inspection system focused on four areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and the generic *E. coli* testing program, and (4) enforcement controls, including the testing program for *Salmonella*. Italy's inspection system was assessed by evaluating these four risk areas.

During all on-site establishment visits, the auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditors also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the audit team leader explained to the CCA that their inspection system would be audited in accordance with three area of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), FSIS auditors would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964. This directive has been declared equivalent under the VEA.

Second, in areas not covered by this directive, FSIS auditors would audit against FSIS requirements. These requirements include daily inspection in processing establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, *E. coli* testing and *Salmonella* testing.

Third, FSIS auditors would audit against any equivalence determinations that have been made by FSIS for Italy under provisions of the Sanitary/Phytosanitary Agreement. Currently, the only equivalence determination Italy has requested regards the use of a different analytical method for testing United States-destined product for *Salmonella*. FSIS has determined that Italy's use of the ISO 6579 and AOAC 967.25 methods are equivalent to FSIS' requirements.

#### 4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following Community Directive was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat

#### 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at [www.fsis.usda.gov/ofo/tsc](http://www.fsis.usda.gov/ofo/tsc).

In the last three FSIS audit reports of Italy's meat inspection system (May 2000, May 2001, and November 2001), a number of problems were identified and the following recommendations from these audits are of special relevance for this audit:

- To strengthen veterinary supervision at all levels to assure compliance with United States requirements.
- To increase the number and scope of inspections of establishments carried out by the CCA, regional offices, and local offices to ensure uniform application of United States requirements in relation to the certification of establishments for export and the maintenance of United States standards in these establishments.
- To institute daily inspection in processing establishments.
- To improve the sanitation of facilities and equipment.
- To ensure the humane slaughter of animals.
- To ensure the implementation of basic HACCP requirements
- To ensure the use of approved methods for analytical testing of samples for *Salmonella* and generic *E. coli*.

#### 6. MAIN FINDINGS

##### 6.1 Legislation

The audit team was informed that the relevant EC Directive, determined equivalent under the VEA, has been transposed into Italian legislation as follows:

- Council Directive 64/433 of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat

## 6.2 Competent Authority Control Systems

FSIS regulations require that foreign countries that wish to become eligible to export meat to the United States or to maintain their current eligibility be organized and administered by the national government. More specifically, there must be organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all establishments producing product for export to the United States. Second, the national government must have ultimate control and supervision over the official activities of all employees and licensees. Third, the national government must ensure the assignment of competent, qualified inspectors. Fourth, national inspection officials must have the authority and responsibility to enforce the laws and regulations governing meat inspection, and fifth, the country must have adequate administrative and technical support to operate its inspection program.

The FSIS auditors noted the following.

The organization of the Italian Veterinary Services consists of three levels: central, regional, and local. At the central level, Veterinary Services is a component of the General Direction of Veterinary Public Health, Food and Nutrition of the Ministry of Health. This is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced. Veterinary Services with regard to meat inspection is staffed with eight personnel. This is an increase of three veterinarians since August 2001. At the regional level, there are 19 veterinary service regions and two autonomous provinces, which supervise the local health units. At the local level, there are 222 local health units (Azienda Sanitaria Locale), which provide inspection services to Italian slaughter, cutting, and processing establishments, including establishments certified for export to the United States. Approximately 5,000 veterinarians are assigned to the local health units. There are generally two levels of employment of inspectors and veterinarians at the local and regional offices. These two levels consist of a director of the regional office or local health office and staff veterinarians.

The audit team was informed of completed, ongoing and planned changes within the CCA with regard to control of inspection activities in Italian meat establishments. Prior to FSIS' May 2000, May 2001 and November 2001 audits, the CCA was in the process of gradually transferring inspection authority to the regional offices, including the authority to certify establishments for export to the United States. As a direct result of findings contained in the three previous FSIS' audits and as a condition to continue Italy's eligibility to export meat products to the United States, the CCA has taken action to regain control over regional and local office activities and has also regained the authority for certifying and decertifying establishments for export to the United States.

The CCA is now responsible for carrying out inspections of individual establishments and for approving and withdrawing the eligibility of individual establishments. In response to an FSIS request for a new list of certified establishments by March 15, 2002, the CCA ordered all regional offices to audit currently certified establishments for compliance with U.S. requirements and to recommend which establishments should remain certified. The CCA then carried out verification audits of all the certified

slaughter establishments, and verification audits of a random sample of certified processing establishments. CCA personnel then determined which establishments met all United States requirements and could be recertified for export. Of the 145 certified establishments as of February 12, 2001, the CCA determined, through its audits, that six slaughter and 76 processing establishments met United States requirements. These 82 establishments were recertified for export to the United States. The remaining 63 establishments were not recertified for export and may not export product to the United States. In addition, a computerized program for tracking the status of all certified establishments has been established at the headquarters of the CCA.

As stated above, the CCA now has the legal authority to supervise the activities of the regional offices. In addition, a reorganization of the CCA has been completed. The reorganization has established a new Office VII--Audit, Relations with Regions—that will be responsible for ongoing audits of all certified establishments. This office will work directly with Office IX—Hygiene of Meat, Fish, Milk, Eggs and other Food of Animal Origin. Office VII has not yet been staffed but it is recommended that a minimum of three veterinarians and two additional personnel will be needed to assure uniform enforcement of United States requirements in all Regions with certified establishments. These figures are based on the number of certified establishments remaining at or below 82.

Additional recommendations regarding staffing and training for Office IX of the CCA, the regional offices, and the local health units are listed at the end of this report. These recommendations are based on the supervision and enforcement of United States requirements in 82 certified establishments and take into consideration European Commission inspection directives which come into effect in June 2002 and which will further strain available resources.

### 6.3 Ultimate Control and Supervision

On February 15, 2002, the CCA sent instructions to all regional offices requesting that they immediately take the actions described in their November 6, 2001 circular and adopt procedures and forms for inspection that meet the provisions in the circular. The February 2002 instructions and the November 2001 circular stressed the procedures to be used for recertifying establishments, the need for daily inspection in processing establishments, reiterated who was responsible for taking *Salmonella* samples, and described the verification activities that would be undertaken by the CCA for establishments proposed for recertification. FSIS auditors verified through audits of the regional and local offices that the instructions and the circular were received by and implemented by these offices.

### 6.4 Assignment of Competent, Qualified Inspectors

The auditors found that that all government veterinarians must have completed at least three years of specialized training in food inspection prior to hiring. Additionally, the regional offices are responsible for developing and approving uniform training courses in HACCP and other food science disciplines. Of every 38 hours worked, veterinarians now receive approximately four hours of additional training as determined by the



regional offices. Training courses for inspectors who are not veterinarians are continuing and increasing.

In addition, the auditors found that most inspectors and veterinarians assigned to certified establishments now understand how to implement and have implemented FSIS' PR/HACCP requirements, which include SSOP, HACCP, generic *E. coli* testing, and *Salmonella* testing in certified establishments.

In contrast to previous audit findings, the auditors found that there is a clear line of supervisory authority and supervision of inspectors and veterinarians in the regional offices and the local offices. Actual visits to determine competence by the regional office are now routinely performed and documented. In addition, written supervisory plans have been developed and are in use for documenting the performance of inspectors and veterinarians.

#### 6.5 Authority and Responsibility to Enforce the Laws

Prior to this audit, the local health offices had the responsibility for approving establishments for export to the U.S. and to withdraw such approval for cause. Subsequent to our November 2001 audit, the MOH assumed this responsibility. Under the direction of the CCA, any new establishment that wishes to export to the U.S. has 90 days to comply with U.S. requirements. The local health office monitors the establishment and then notifies the CCA, either through the regional office or directly, of the decision to certify or not certify the establishment for U.S. export. The CCA will visit these establishments on-site and will determine if the establishment can be certified for export. As discussed earlier, the CCA is in the process of setting up a headquarters audit staff whereby personnel will conduct verification audits at least twice each year of all certified establishments to ensure that the establishments continue to meet all U.S. and European Union requirements.

#### 6.6 Adequate Administrative and Technical Support

During this audit, the auditors found that the CCA has acquired appropriate resources to support a third party audit. This finding is in direct contrast to the finding of the November 2001 audit whereby resources were not available to support a third party audit.

### 7. ESTABLISHMENT AUDITS

FSIS auditors visited 41 establishments in total—six slaughter establishments and 35 processing establishments. None were delisted as a result of the reviews.

### 8. LABORATORY AUDITS

During the laboratory audits, emphasis was placed on two specific areas. The first area was the use of the correct analytical method for testing field samples for generic *E. coli*. The second area was the use of the correct analytical method for testing field samples for *Salmonella*.

The following government laboratories were reviewed. Each of these laboratories performs or plans to perform analytical testing on field samples for product destined for the United States.

- Istituto Zooprofilattico, Rome
- Istituto Zooprofilattico, Modena
- Istituto Zooprofilattico, Mantova
- Istituto Zooprofilattico, Brescia

Three of the four laboratories audited were found to be using the correct analytical methods for testing field samples for generic *E. coli* and *Salmonella*. However, one laboratory was using modified versions of the correct analytical methods for generic *E. coli* and *Salmonella*. The modifications to the testing methods had not been submitted to FSIS for an equivalence determination.

## 9. SANITATION CONTROLS

As stated earlier, FSIS auditors focused on four areas of risk to assess Italy's meat inspection system. The first of these risk areas that FSIS auditors reviewed was Sanitation Controls.

Based on the on-site audits of establishments, Italy's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices. In addition, Italy's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

### 9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in the 41 establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies.

- In three establishments, product contact equipment was not properly cleaned.

### 9.2 EC Directive 64/433

In 33 establishments, the provisions of EC Directive 64/433 were effectively implemented. In the eight establishments with deficiencies, there were no noted trends, the deficiencies were not repeat, and the inspection officials took immediate corrective action. Specific deficiencies are noted in the attached individual establishment reports.

## 10. ANIMAL DISEASE CONTROLS

The second of the four risk areas that the FSIS auditors reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over

condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditors determined that Italy's inspection system had adequate controls in place. No deficiencies were noted.

## 11. SLAUGHTER/PROCESSING CONTROLS

The third of the four risk areas that the FSIS auditors reviewed was Slaughter/Processing Controls. The controls include the following areas: adequate animal identification; ante-mortem inspection procedures; ante-mortem disposition; humane slaughter; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products. The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments.

### 11.1 HACCP Implementation.

All establishments approved to export meat products to the U.S. are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the 41 establishments. Thirty-five establishments had adequately implemented the PR/HACCP requirements.

### 11.2 Testing for Generic *E. coli*

Italy has adopted the FSIS regulatory requirements for generic *E. coli* testing. Six of the 41 establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing. These six establishments were evaluated according to the criteria employed in the U.S. domestic inspection program.

Generic *E. coli* testing was properly conducted in five of the six slaughter establishments. However, in one slaughter establishment, one of the sampling sites was not correct despite the presence of four government veterinarians assigned to this establishment.

### 11.3 EC Directive 64/433

In all establishments, the provisions of EC Directive 64/433 were effectively implemented.

## 12. ENFORCEMENT CONTROLS

The last of the four risk areas that the FSIS auditors reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing. Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

### 12.1 Testing for *Salmonella*

Prior to this audit Italy had advised FSIS that it had adopted all of the FSIS requirements for *Salmonella* species testing with the sole exception of the use of different analytic methods. FSIS had determined that Italy's use of the ISO 6579 or AOAC 967.25 methods were equivalent to FSIS' requirements.

Six of the 41 establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the United States domestic inspection program. No deficiencies were noted.

### 12.2 Species Verification Testing

At the time of this audit, Italy was required to test product for species verification. Species verification testing was being conducted in those establishments required to test for species verification.

### 12.3 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required. These reviews were being performed by officials from the regional or local offices. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the regional and provincial offices.

### 12.4 Inspection System Controls

#### 12.4.1 Daily Inspection in Processing Establishments

The auditors found that daily inspection had been instituted in all certified processing establishments.

### 12.5 Investigations

Italy's Carabinieri Per La Sanita (Public Health Police) is responsible for the oversight of the production, packaging, distribution, sale and transportation of food and beverages. It

also investigates alleged violations of Italy's meat inspection laws, regulations and circulars. The force was established in 1962. In 1996, the force was increased in both numbers and responsibility in response to continuing findings of improper activities in food production, distribution and storage. The director of the office reports directly to the Minister of Health. The force consists of approximately 1000 officers. For those officers involved in food investigations, they must first be certified police officers and second must pass qualifications to be a health inspector. The force reports violations directly to the appropriate Magistrate, and their investigation reports are sent directly to the Italian prosecutor's office. Of special note is the fact that each of these officers has the authority to shut down an establishment on the spot for violations of meat inspection laws, regulations or circulars.

### 13. RECOMMENDATIONS

To ensure continuing enforcement of United States requirements in certified establishments and because of new European Commission inspection requirements effective June 2002, FSIS has the following recommendations. These recommendations are based on the workload for the existing 82 establishments certified for export to the U.S.

- Increase staffing for Office IX—Hygiene of Meat, Fish, Milk, Eggs and Other Food of Animal Origin to include three additional veterinarians
- Staff the new Office VII—Audit, Relations with Regions with at least five staff members including three veterinarians
- Add additional staff at the regional level

With regard to training, FSIS recommends the following:

- Participation of representatives of both Office IX and the new Office VII in training activities planned for August 2002 in Washington, DC
- Development of a protocol for use by the CCA and FSIS to audit regional and local health units
- Use of video conferences with laboratories to share scientific information
- Scheduling of additional training for regional officials and local inspectors
- Quarterly meetings of CCA staff and regional officials to plan training activities and assure enforcement of United States requirements

General Recommendations:

- The CCA should audit all regional offices prior to the next FSIS audit, which is scheduled for the fall of 2002.
- The CCA should strengthen its oversight of laboratories that analyze samples from certified establishments.
- The CCA should require that the Istituto Zooprofilattico in Rome submit its modified *Salmonella* and generic *E. coli* testing methods to FSIS for an equivalence determination prior to use of the modified methods.

#### 14. CLOSING MEETING

A closing meeting was held on May 13, 2002 with the CCA, Ministry of Health, Department of Food, Nutrition and Public Veterinary Health. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the audit team leader. In addition, the team leader advised the CCA that she would recommend to FSIS that as a result of the audit findings the CCA should again be permitted to certify establishments for export to the United States, that 100 percent reinspection of Italian meat products at U.S. ports of entry be discontinued, and that Italy be returned to a routine audit schedule beginning in the fall of 2002.

The CCA understood and accepted the findings.

Dr. Sally Stratmoen  
Audit Team Leader

(signed) Dr. Sally Stratmoen

## ATTACHMENTS

Individual Foreign Establishment Audit Forms

Written Foreign Country's Response to the Draft Final Audit Report